Key References

Day 1

Session 1 Overview of Public Health Needs and Regulatory Requirements for Vaccine Testing

8:50 History and Overview of Human Vaccines and their Importance to Public Health

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9:15 History and Overview of Veterinary Vaccines and their Importance to Animal Health

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9:40 U.S. FDA Requirements for Human Vaccine Safety and Potency Testing

21 CFR Parts 600 through 680

Cussler K, Kulpa J, Calver J. 2002. The international symposium on regulatory testing and animal welfare: recommendations on best scientific practices for biologicals: safety and potency evaluations. ILAR J. 43(suppl):S126-128.

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10:00 USDA Requirements for Veterinary Vaccine Safety and Potency Testing

21 CFR Parts 600 through 680

10:40 International Regulatory Requirements for Vaccine Safety and Potency Testing: Roundtable Discussion

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Session 2 Replacement Methods for Vaccine Potency Testing: Current State of the Science and Knowledge Gaps

11:20 Overview of Currently Approved Veterinary Vaccine Potency Testing Methods and Methods in Development That Do Not Require Animal Use

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11:45 Case Study of Development, Validation, and Acceptance of a Non-Animal Method for Assessing Veterinary Vaccine Potency

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1:10 Overview of Currently Approved Human Vaccine Potency Testing Methods That Do Not Require Animal

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1:35 Overview of The Current Status of Human Vaccine Potency Testing Methods in Development That May Replace Animals

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2:00 Case Study of Development, Validation, and Acceptance of a Non-Animal Method for Assessing Human Vaccine Potency

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Day 2

Session 3 Animal Use for Vaccine Potency Testing: Refinement and Reduction Alternatives

Session 3A: Refinement Alternatives: Using Serological Methods to Avoid Challenge Testing

9:35 Refinement Alternatives for Human Vaccine Potency Testing: Overview of Currently Approved Serological Methods

10:00 Refinement Alternatives for Veterinary Vaccine Potency Testing: Overview of Currently Approved Serological Methods

10:45 Animal Refinement and Reduction Alternative Approaches for Vaccine Potency Testing of Diphtheria and Tetanus Vaccines

Kumar S, Kanwar S, Bansal V, Sehgal R. 2009. Standardization and validation of Vero cell assay for potency estimation of diphtheria antitoxin serum. Biologicals. 37:297-305.

11:10 Development and Validation of Serological Methods for Human Vaccine Potency Testing: Case Study of an Anthrax Vaccine

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11:35 Development and Validation of Serological Methods for Veterinary Vaccine Potency Testing: Case Study of a Veterinary Vaccine

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Session 3B: Refinement Alternatives: Using Earlier Humane Endpoints to Avoid or Minimize Animal Pain and Distress in Vaccine Potency Challenge Testing

1:00 Overview of Current Humane Endpoints in Human and Veterinary Vaccine Potency Testing

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1:50 Application of the Consistency Approach for Reducing Animal Use in Vaccine Potency Testing

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Day 3

Session 4 Vaccine Safety Testing: Post-Licensing Reduction, Refinement and Replacement Methods and Strategies

9:35 Human Vaccine Post-license Safety Testing: Overview of Current Regulatory Requirements and Accepted Alternatives

Cussler K, Kulpa J, Calver J. 2002. The international symposium on regulatory testing and animal welfare: recommendations on best scientific practices for biologicals: safety and potency evaluations. ILAR J. 43(suppl):S126-128.

10:00 Veterinary Vaccine Post-License Safety Testing: Overview of Current Regulatory Requirements and Accepted Alternatives

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10:55 Target Alternative Vaccine Safety Testing Strategies for Pertussis Toxin

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11:20 Current Research and Development Activities Directed Toward Replacement of the Neurovirulence Test in Vaccine Safety Testing

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